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Attorneys for Plaintiff  
SANDOZ INC.

**UNITED STATES DISTRICT COURT**  
**CENTRAL DISTRICT OF CALIFORNIA**  
**WESTERN DIVISION**

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC.,

Defendant.

Case No. 2:22-cv-05326-RGK-JEM

[DISCOVERY MATTER: Referred to  
Magistrate Judge John. E. McDermott]

**STIPULATED PROTECTIVE ORDER**

STIPULATED PROTECTIVE ORDER

1 **1. GENERAL**

2 **A. PURPOSES AND LIMITATIONS**

3 Discovery in this action is likely to involve production of confidential,  
4 proprietary, trade secret, or private information for which special protection from  
5 public disclosure and from use for any purpose other than prosecuting this litigation  
6 may be warranted. Accordingly, Plaintiff Sandoz Inc. (“Sandoz” or “Plaintiff”) and  
7 Defendant Amgen Inc. (“Amgen” or “Defendant”) (collectively “the Parties” and  
8 each individually a “Party”) hereby stipulate to, and request the Court enter, this  
9 Stipulated Protective Order. The Parties acknowledge that this Order does not confer  
10 blanket protections on all disclosures or responses to discovery and that the protection  
11 it affords from public disclosure and use extends only to the limited information or  
12 items that are entitled to confidential treatment under the applicable legal principles.

13 **B. GOOD CAUSE STATEMENT**

14 This action is likely to involve customer information, pricing lists and other  
15 valuable research, development, commercial, financial, technical, and/or proprietary  
16 information for which special protection from public disclosure and from use for any  
17 purpose other than the litigation of this action is warranted. Such confidential and  
18 proprietary materials and information may consist of, among other things,  
19 confidential business or financial information, information regarding confidential  
20 business practices, or other confidential research, development, trade secrets,  
21 Personally Identifiable Information, Protected Health Information, or commercial  
22 information, information otherwise generally unavailable to the public, or which may  
23 be privileged or otherwise protected from disclosure under state or federal statutes,  
24 court rules, case decisions, or common law, or other protected information the  
25 disclosure of which the Producing Party in good faith believes would likely cause  
26 harm. Accordingly, to expedite the flow of information, to facilitate the prompt  
27 resolution of disputes over confidentiality of discovery materials, to adequately  
28 protect information the Parties are entitled to keep confidential, to ensure that the

1 Parties are permitted reasonably necessary uses of such material in preparation for  
2 and in the conduct of the trial of this action, to address their handling at the end of the  
3 litigation, and to serve the ends of justice, a Protective Order for such information is  
4 justified in this matter. It is the intent of the Parties that information will not be  
5 designated as Protected Material for tactical reasons and that nothing be so designated  
6 without a good faith belief that it has been maintained in a confidential, non-public  
7 manner, and there is good cause as to why it should not be part of the public record  
8 of this case.

9 **C. ACKNOWLEDGEMENT OF PROCEDURE FOR FILING UNDER**  
10 **SEAL**

11 The Parties further acknowledge, as set forth in Section 11.3, below, that this  
12 Stipulated Protective Order does not entitle them to file confidential information  
13 under seal; Local Civil Rule 79-5 sets forth the procedures that must be followed and  
14 the standards that will be applied when a Party seeks permission from the court to file  
15 material under seal.

16 **2. DEFINITIONS**

17 2.1 Action: This pending federal lawsuit, Case No. 2:22-cv-05326-RGK-  
18 JEM (C.D. Cal.).

19 2.2 Challenging Party: A Party that challenges the designation of  
20 information or items under this Order.

21 2.3 CONFIDENTIAL Information or Items: Information (regardless of how  
22 generated, stored, or maintained) or tangible things that qualify for protection under  
23 Federal Rule of Civil Procedure 26(c). Material that is available to the public,  
24 including advertising or promotional materials and the like, shall not be designated  
25 “CONFIDENTIAL.”

26 2.4 Designating Party: A Party or Non-Party that designates information or  
27 items that it produces in disclosures or in responses to discovery as CONFIDENTIAL  
28 or HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY.

1           2.5    Disclosure or Discovery Material: All items or information, regardless  
2 of the medium or manner in which it is generated, stored, or maintained (including,  
3 among other things, testimony, transcripts, and tangible things), that are generated in  
4 this matter or produced in it.

5           2.6    Expert: A person with specialized knowledge or experience in a matter  
6 pertinent to the litigation who has been engaged by a Party or its counsel to serve as  
7 an expert witness or as a consultant in this Action.

8           2.7    Non-Party: Any natural person, partnership, corporation, association, or  
9 other legal entity not a Party to this action.

10          2.8    Outside Counsel of Record: Attorneys who are not employees of a Party  
11 to this Action but are retained to represent or advise a Party to this Action and have  
12 appeared in this Action on behalf of that Party or are affiliated with a law firm that  
13 has appeared on behalf of that Party, including support staff at any such law firm.

14          2.9    Party: Any Party to this Action, including all of its officers, directors,  
15 employees, consultants, Experts, and Outside Counsel of Record (and their support  
16 staffs).

17          2.10   Personally Identifiable Information (PII): For purposes of this Order, PII  
18 includes, but is not limited to: payment card numbers, financial account numbers,  
19 social security numbers, addresses, phone numbers, e-mail addresses, driver's license  
20 numbers or other state identification numbers, employer identification numbers, tax  
21 identification numbers, passport numbers, or a foreign government equivalent of any  
22 of these numbers or identifiers. The Parties recognize that other personal data (e.g.,  
23 name, citizenship, birth date, spousal, and familial information), particularly in  
24 combination with other information, may reveal sensitive PII and, for purposes of this  
25 Order, PII also includes such data when in combination with other information.

26          2.11   Privileged Material: Information protected by the attorney-client  
27 privilege, work product doctrine, or other recognized privilege against disclosure in  
28 discovery.

1           2.12 Producing Party: A Party or Non-Party that produces Disclosure or  
2 Discovery Material in this Action.

3           2.13 Professional Vendors: Persons or entities that provide litigation support  
4 services (*e.g.*, photocopying, videotaping, translating, transcribing, preparing exhibits  
5 or demonstrations, and organizing, storing, or retrieving data in any form or medium)  
6 and their employees and subcontractors.

7           2.14 Protected Health Information (PHI): For purposes of this Order, PHI  
8 includes all individually identifiable health information, including demographic data,  
9 medical histories, test results, insurance information, and other information used to  
10 identify a patient or provide healthcare services or healthcare coverage.

11           2.15 Protected Material: Any Disclosure or Discovery Material that is  
12 designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - ATTORNEYS’  
13 EYES ONLY.”

14           2.16 Qualified Person: No more than two specifically-designated “In-House  
15 Counsel” (of the Receiving Party) per Party. “In-House Counsel” is defined as U.S.  
16 attorneys admitted to practice in the U.S and who do not have a competitive decision-  
17 making function as part of their job responsibilities. Such In-House Counsel shall  
18 have a need to know the Designated Information to fulfill his or her duties and  
19 responsibilities in connection with this Action, and meet the requirements of  
20 Paragraph 6.5, as well as paralegals, assistants, in-house information technology  
21 providers, and clerical employees who support such in-house personnel. For each  
22 respective Party, the specifically identified In-House Counsel and their titles are set  
23 forth as follows (if not listed below, names and titles will be provided at least five (5)  
24 business days prior to any such In-House Counsel being provided access to  
25 CONFIDENTIAL or HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY  
26 Information):

27           i. For Amgen:

28                   1. Kimberly Dunne (Vice President, Law)

2. Diane Mendez (Senior Counsel)

ii. For Sandoz:

1. Gordon Hwang (Head NA Litigation & Investigations,  
P&O Legal)

2. [NAME]

2.17 Receiving Party: A Party that receives Disclosure or Discovery Material from a Producing Party.

2.18 HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
Information or Items: Information (regardless of how generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c) or other applicable law, and is so sensitive that its dissemination would put the Producing Party at a competitive disadvantage and/or compromise the Producing Party's business interests such that it deserves even further limitation.

### **3. SCOPE**

The protections conferred by this Stipulated Protective Order cover not only Protected Material (as defined above), but also: (1) any information copied or extracted from Protected Material; (2) all copies, excerpts, summaries, or compilations of Protected Material; and (3) any testimony, conversations, or presentations by Parties or their Counsel that might reveal Protected Material.

This Order does not govern the use of Protected Material at trial. Use of Protected Material at trial shall be governed by the orders of the trial judge.

### **4. DESIGNATING PROTECTED MATERIAL**

4.1 Exercise of Restraint and Care in Designating Material for Protection. Each Party or Non-Party that designates information or items for protection under this Order must take reasonable steps to limit designations to specific material that qualifies under the appropriate standards.

4.2 Manner and Timing of Designations. Except as otherwise provided in this Order (*see, e.g.*, second paragraph of Section 4.2(a), below), or as otherwise

1 stipulated or ordered, Disclosure or Discovery Material that qualifies for protection  
2 under this Order should be clearly so designated before the material is disclosed or  
3 produced.

4 Designation in conformity with this Order requires:

5 (a) for information in documentary form (*e.g.*, paper or  
6 electronic documents, but excluding transcripts of depositions or other  
7 pretrial or trial proceedings), that the Producing Party affix at a  
8 minimum, the legend “CONFIDENTIAL” or “HIGHLY  
9 CONFIDENTIAL - ATTORNEYS’ EYES ONLY” (hereinafter  
10 “DESIGNATION legend”), to each page that contains protected  
11 material.

12 A Party or Non-Party that makes original documents available for  
13 inspection need not designate them for protection until after the  
14 inspecting Party has indicated which documents it would like copied and  
15 produced. During the inspection and before the designation, all of the  
16 material made available for inspection shall be deemed “HIGHLY  
17 CONFIDENTIAL - ATTORNEYS’ EYES ONLY” unless the Parties  
18 agree to some lesser designation. After the inspecting Party has identified  
19 the documents it wants copied and produced, the Producing Party must  
20 determine which documents, or portions thereof, qualify for protection  
21 under this Order. Then, before producing the specified documents, the  
22 Producing Party must affix the “DESIGNATION legend” to each page  
23 that contains Protected Material.

24 (b) For depositions and the information contained in  
25 depositions, a Party must designate the whole transcript or portions of  
26 the transcript (including exhibits) that contain CONFIDENTIAL or  
27 HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY  
28 Information by sending a letter—within thirty days of receiving the

1 deposition transcript—that identifies the designated testimony by page  
2 and line number. If the testimony discloses the contents of Protected  
3 Material that a Non-Party has designated as CONFIDENTIAL or  
4 HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY, then the  
5 person taking the deposition must consult that Non-Party to determine  
6 whether the affected portions of the testimony should be designated as  
7 CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’  
8 EYES ONLY. The Parties must treat the entire deposition transcript  
9 (including exhibits) as CONFIDENTIAL under this Protective Order  
10 until the expiration of the above-referenced thirty-day period, but if the  
11 deposition contained, referenced, or disclosed information that a Party  
12 designated as HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES  
13 ONLY, then the Parties must treat the entire deposition transcript  
14 (including exhibits) as HIGHLY CONFIDENTIAL – ATTORNEYS’  
15 EYES ONLY until the expiration of the thirty-day period. The notation  
16 “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’  
17 EYES ONLY” shall be placed on the front of the deposition transcript,  
18 or if the deposition is videorecorded, on a DVD or other item containing  
19 a video file, or placed in the file name for an electronic copy of the  
20 transcript or video. The designation will apply only to those portions of  
21 the deposition that the Party designates as CONFIDENTIAL or  
22 HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.  
23 Designated parts are not to be used, copied, or disclosed except as  
24 authorized by this Order. Counsel who retains court reporters or  
25 videographers must ensure their compliance with this paragraph.

26 (c) For information produced in some form other than  
27 documentary and for any other tangible items, that the Producing Party  
28 affix in a prominent place on the exterior of the container or containers



1 in which the information is stored the legend “CONFIDENTIAL” or  
2 “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY.” If only  
3 a portion or portions of the information warrants protection, the  
4 Producing Party, to the extent practicable, shall identify the protected  
5 portion(s).

6 4.3 Failures to Designate. As further discussed in Section 10, *infra*, A failure  
7 to designate qualified information or items at the time of production or disclosure  
8 does not waive the Designating Party’s right to secure protection under this Order for  
9 such material. Upon timely correction of a designation, the Receiving Party must treat  
10 the material in accordance with the provisions of this Order.

11 4.4 Redesignation. Any Producing Party may designate or redesignate (or  
12 withdraw a designation regarding) any material (“Redesignated Material”) that it has  
13 produced; provided, however, that such redesignation shall be effective only as of the  
14 date of such redesignation. Such redesignation (or withdrawal) shall be accomplished  
15 by notifying counsel for each party in writing of such redesignation (or withdrawal)  
16 or, if at a deposition, by notifying counsel on the record at the deposition, and by  
17 reproducing promptly the material with the redesignation. Upon receipt of any such  
18 notice of redesignation, counsel shall: (i) not make any further disclosure or  
19 communication of such Redesignated Material except as provided for in this  
20 Protective Order; (ii) take reasonable steps to notify any persons known to have  
21 possession of any Redesignated Material of the treatment of such material required  
22 under this Protective Order pursuant to the redesignation; and (iii) promptly endeavor  
23 to procure all copies of such Redesignated Material from any persons known to have  
24 possession of any such Redesignated Material who are not entitled to receipt under  
25 the applicable paragraph governing disclosure of the Redesignated Material.

## 26 **5. CHALLENGING CONFIDENTIALITY DESIGNATIONS**

27 5.1 Timing of Challenges. Any Party or Non-Party may challenge a  
28 designation of confidentiality at any time that is consistent with the Court’s

1 Scheduling Order.

2 5.2 Meet and Confer. The Challenging Party shall initiate the dispute  
3 resolution process under Local Rule 37.1 et seq.

4 5.3 Burden. Unless the Designating Party has withdrawn the confidentiality  
5 designation, all Parties shall continue to afford the material in question the level of  
6 protection to which it is entitled under the Producing Party's designation until the  
7 Court rules on the challenge.

8 **6. ACCESS TO AND USE OF PROTECTED MATERIAL**

9 6.1 Basic Principles. A Receiving Party may use Protected Material that is  
10 disclosed or produced by another Party or by a Non-Party in connection with this  
11 Action only for prosecuting, defending, or attempting to settle this Action. Such  
12 Protected Material may be disclosed only to the categories of persons and under the  
13 conditions described in this Order. When the Action has been terminated, a Receiving  
14 Party must comply with the provisions of Section 12 below (FINAL DISPOSITION).

15 Protected Material must be stored and maintained by a Receiving Party at a  
16 location and in a secure manner that ensures that access is limited to the persons  
17 authorized under this Order.

18 6.2 Disclosure of "CONFIDENTIAL" Information or Items. Unless  
19 otherwise ordered by the Court or permitted in writing by the Designating Party, a  
20 Receiving Party may disclose any information or item designated  
21 "CONFIDENTIAL" only to:

22 (a) the Receiving Party's Outside Counsel of Record in this Action, as well as  
23 employees of said Outside Counsel of Record to whom it is reasonably necessary to  
24 disclose the information for this Action;

25 (b) the officers, directors, and employees of each Party, including the in-house  
26 lawyers of each Party and their secretaries and paralegal assistants, to the extent  
27 reasonably necessary for the litigation of this Action, provided that each such  
28 employee representative has agreed to be bound by the provisions of the Protective

1 Order by signing a copy of the “Acknowledgement and Agreement to Be Bound”  
2 attached as Exhibit A;

3 (c) outside consultants or Experts (i.e., not existing employees or affiliates of a  
4 Party) engaged for the purpose of assisting in this Action, provided that they have  
5 previously executed the ‘Acknowledgement and Agreement to Be Bound’ attached as  
6 Exhibit A hereto and: (1) do not have direct responsibility and, at the time of  
7 engagement, do not intend to have direct responsibility, for advising on, planning,  
8 preparing, or prosecuting patent applications including claims relating to  
9 pegfilgrastim or pegfilgrastim biosimilar products; (2) are not involved in and, at the  
10 time of engagement, do not intend to be involved in, final competitive decision-  
11 making, such as developing business plans or commercial strategies, for a company  
12 with respect to pegfilgrastim or pegfilgrastim biosimilar products (*see* Section 6.5(c),  
13 *infra*); or (3) do not and, at the time of engagement, do not intend to, advise on, plan,  
14 prepare, or submit documents, including any Citizen Petition, to the FDA that would  
15 interfere with Amgen’s Neulasta® or Sandoz’s Ziextenzo® or negatively affect  
16 Neulasta® or Ziextenzo®;

17 (d) the Court and its personnel;

18 (e) court reporters and their staff;

19 (f) independent litigation support services, including persons working for or as  
20 court reporters, translators, graphics or design services, jury or trial consulting  
21 services, and photocopy, document imaging, and database services retained by  
22 counsel and reasonably necessary to assist counsel with the litigation of this Action;

23 (g) any person from whom testimony is taken, where such person was the  
24 author or recipient of the Protected Material, or is the Producing Party’s present  
25 officer, director, or employee;

26 (h) during their depositions, witnesses, and attorneys for witnesses, in the  
27 Action to whom disclosure is reasonably necessary provided: (1) the deposing Party  
28 requests that the witness sign the form attached as Exhibit A hereto; and (2) they will

1 not be permitted to keep any confidential information unless otherwise agreed by the  
2 Designating Party or ordered by the Court; and

3 (i) any mediator or settlement officer, and their supporting personnel, mutually  
4 agreed upon by any of the Parties engaged in settlement discussions.

5 6.3 Disclosure of “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES  
6 ONLY” Information or Items. Unless otherwise ordered by the Court or permitted in  
7 writing by the Designating Party, a Receiving Party may disclose any information or  
8 item designated “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY” only  
9 to the individuals listed in Section 6.2 (a) and (c) – (i), and to the Qualified Persons  
10 identified above in Section 2.16, provided that such Qualified Person has agreed to be  
11 bound by the provisions of this Protective Order by signing the “Acknowledgement  
12 and Agreement to Be Bound” attached as Exhibit A hereto.

13 6.4. Storage of Protected Material. Protected Material must be stored and  
14 maintained by a Receiving Party at a location and in a secure manner that ensures  
15 that access is limited to the persons authorized under this Order. Receiving Parties  
16 shall exercise at least the same degree of care in the storage, custody, or use of  
17 Protected Material as they would apply to their own material of the same or  
18 comparable confidentiality and sensitivity but in no event less than a reasonable  
19 degree of care. Receiving Parties must take reasonable precautions to protect  
20 Protected Material from loss, misuse and unauthorized access, disclosure, alteration,  
21 and destruction, including but not limited to:

22 (a) Protected Material in electronic form shall be maintained in a secure  
23 litigation support site that applies standard industry practices regarding data  
24 security, including but not limited to application of access control rights to those  
25 persons entitled to access Protected Material under this Order;

26 (b) A list of current and former authorized users of the Receiving Party’s  
27 litigation support site shall be maintained while this Action, including any appeal,  
28 is pending;

1 (c) Protected Material downloaded from the litigation support site in  
2 electronic format shall be stored or shipped only on devices or media (e.g., laptop,  
3 tablet, smartphone, USB drive) that are encrypted with access limited to persons  
4 entitled to access Protected Material under this Order;

5 (d) Protected Material in paper format shall be maintained in the Receiving  
6 Party's Outside Counsel of Record's law offices or comparably secure location,  
7 with access limited to persons entitled to access Protected Material under this  
8 Protective Order;

9 (e) Electronic delivery of Protected Material shall be by encrypted Secure  
10 File Transfer Protocol or similar secure electronic transmission or encrypted email  
11 addressed only to persons entitled to access Protected Material under this Order;

12 (f) Physical shipments of Protected Material shall be by courier and  
13 securely sealed and addressed only to persons entitled to access Protected  
14 Material under this Order; and

15 (g) If a data breach that includes Protected Material occurs or a Receiving  
16 Party reasonably believes such a breach may have occurred, the Receiving Party  
17 shall immediately report such incident to the Producing Party, describe the  
18 Protected Material accessed, and use best efforts to return to the Producing Party  
19 the Protected Material accessed. The Receiving Party shall also immediately take  
20 such actions the Producing Party requests in good faith to remediate the breach,  
21 to preclude further breaches, and take such actions that are required by applicable  
22 laws, including privacy laws. In no event is a Producing Party ceding notification  
23 or remedial rights in the event of a breach.

24 6.5. Restrictions on Qualified Persons under Sections 2.16 and 6.3. A  
25 Qualified Person having access to "CONFIDENTIAL" or "HIGHLY  
26 CONFIDENTIAL – ATTORNEYS' EYES ONLY" Information or Items shall not:

27 (a) Have direct responsibility for advising on, planning, preparing, or  
28 prosecuting patent applications including claims relating to pegfilgrastim or

1 pegfilgrastim-bmez<sup>1</sup> for a period of two (2) years after the end of this Action,  
 2 including any appeal(s). The provisions of this paragraph do not prevent such  
 3 Qualified Person from representing a party before a domestic or foreign patent agency  
 4 in any reissue, interference, *inter partes* review, post-grant review, or reexamination  
 5 proceeding, subject to the claim-drafting bar in the preceding sentence. Nor do the  
 6 provisions of this paragraph prevent a Qualified Person from assisting a receiving  
 7 party in complying with the requirements of 37 C.F.R. § 1.56, again subject to the  
 8 claim-drafting bar described above.

9 (b) Be involved in final competitive decision-making, such as developing  
 10 business plans or commercial strategies, for a party or any of its affiliates, with respect  
 11 to products that include pegfilgrastim or pegfilgrastim-bmez. For clarity, legal  
 12 decision-making, including without limitation, (i) supervising, negotiating, or  
 13 executing a settlement agreement, including supervising, negotiating, or advising on  
 14 any financial terms of such an agreement or advising about launch dates, (ii) providing  
 15 advice as to whether a particular product design is legally permissible, including  
 16 whether a particular product design would infringe intellectual property rights, (iii)  
 17 supervising, negotiating, or advising on legal aspects of launch strategy, biosimilar  
 18 entry, or regulatory matters regarding a Party's pegfilgrastim or pegfilgrastim-bmez  
 19 products, or (iv) providing general legal advice to a Party regarding pegfilgrastim or  
 20 pegfilgrastim-bmez therapies, shall not be deemed "competitive decision-making."

21 (c) Advise on, plan, prepare, or submit documents, including any Citizen  
 22 Petition, to the FDA that would interfere with Sandoz's Ziextenzo® or Amgen's  
 23 Neulasta®, or negatively affect Ziextenzo® or Neulasta® for the duration of this  
 24 Action and for two (2) years after the end of this litigation, including any appeal(s).  
 25 For clarity, a Qualified Person shall be permitted to counsel their party concerning  
 26

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27  
 28 <sup>1</sup> The use of "pegfilgrastim" or "pegfilgrastim-bmez" in this Order has no  
 impact on the Parties' positions in the Action regarding the meaning of these terms.

activities required to obtain or maintain the Party's regulatory approvals, including but not limited to responding to or commenting on Citizen Petitions and/or FDA correspondence that would affect the regulatory status of the Party's own BLA or aBLA. A Qualified Person shall not use or rely upon "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" Information produced by any other party to counsel their Party concerning activities required to obtain or maintain regulatory approvals.

6.6 Permissible use of Protected Material. This Protective Order does not prevent any person or Party from making use of any Protected Material if the information (i) was lawfully in his or her possession before he or she received it under this Order; (ii) was or becomes available to the public through no fault of a Receiving Party; (iii) was or is lawfully obtained from another source not under an obligation of secrecy to the Producing Party or to any Party claiming ownership of the Protected Material; or (iv) is exempted from this Order by the written consent of the Party owning the Protected Material.

## **7. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION**

If a Party is served with a subpoena or a Court order issued in other litigation that compels disclosure of any information or items designated in this Action as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY" that Party must:

(a) promptly notify in writing the Designating Party. Such notification shall include a copy of the subpoena or Court order;

(b) promptly notify in writing the Party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order. Such notification shall include a copy of this Stipulated Protective Order; and

(c) cooperate with respect to all reasonable procedures sought to be pursued by



1 the Designating Party whose Protected Material may be affected.

2 If the Designating Party timely seeks a Protective Order, the Party served with  
 3 the subpoena or Court order shall not produce any information or items designated in  
 4 this action as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - ATTORNEYS’  
 5 EYES ONLY” before a determination by the court from which the subpoena or order  
 6 issued, unless the Party has obtained the Designating Party’s permission. The  
 7 Designating Party shall bear the burden and expense of seeking protection in that court  
 8 of its confidential material and nothing in these provisions should be construed as  
 9 authorizing or encouraging a Receiving Party in this Action to disobey a lawful  
 10 directive from another court.

11 **8. A NON-PARTY’S PROTECTED MATERIAL SOUGHT TO BE**  
 12 **PRODUCED IN THIS LITIGATION**

13 (a) The terms of this Order are applicable to information produced by a Non-  
 14 Party in this Action and designated as “CONFIDENTIAL” or “HIGHLY  
 15 CONFIDENTIAL - ATTORNEYS’ EYES ONLY.” Such information produced by  
 16 Non-Parties in connection with this litigation is protected by the remedies and relief  
 17 provided by this Order. Nothing in these provisions should be construed as prohibiting  
 18 a Non-Party from seeking additional protections.

19 (b) When serving subpoenas on Non-Parties, the Parties shall include a copy  
 20 of this Order. Non-Parties who produce information in this Action may avail  
 21 themselves of this Order. Likewise, a Party upon reviewing information disclosed  
 22 subject to a third-party subpoena shall, within a reasonable time after receipt of the  
 23 documents produced by the third-party, have the right to designate such documents  
 24 as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES  
 25 ONLY.”

26 (c) In the event that a Party is required, by a valid discovery request, to produce  
 27 a Non-Party’s confidential information in its possession, and the Party is subject to an  
 28 agreement with the Non-Party not to produce the Non-Party’s confidential



1 information, then the Party shall:

2 (1) promptly notify in writing the Requesting Party and the Non-Party that  
3 some or all of the information requested is subject to a confidentiality  
4 agreement with a Non-Party;

5 (2) promptly provide the Non-Party with a copy of the Stipulated Protective  
6 Order in this Action, the relevant discovery request(s), and a reasonably  
7 specific description of the information requested; and

8 (3) make the information requested available for inspection by the Non-Party,  
9 if requested.

10 (d) If the Non-Party fails to seek a Protective Order from this Court within 14  
11 days of receiving the notice and accompanying information, the Receiving Party may  
12 produce the Non-Party's confidential information responsive to the discovery request.  
13 If the Non-Party timely seeks a Protective Order, the Receiving Party shall not  
14 produce any information in its possession or control that is subject to the  
15 confidentiality agreement with the Non-Party before a determination by the Court.  
16 Absent a Court order to the contrary, the Non-Party shall bear the burden and expense  
17 of seeking protection in this Court of its Protected Material.

18 **9. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL**

19 If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed  
20 Protected Material to any person or in any circumstance not authorized under this  
21 Stipulated Protective Order, the Receiving Party must immediately (a) notify in  
22 writing the Designating Party of the unauthorized disclosures, (b) use its best efforts  
23 to retrieve all unauthorized copies of the Protected Material, (c) inform the person or  
24 persons to whom unauthorized disclosures were made of all the terms of this Order,  
25 and (d) request such person or persons to execute the "Acknowledgment and  
26 Agreement to Be Bound" that is attached hereto as Exhibit A.

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1 **10. PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED**  
 2 **MATERIAL**

3 (a) This Order invokes the protections afforded by Rule 502(d) of the Federal  
 4 Rules of Evidence. Accordingly, the provisions in Rule 502(b) will not apply to the  
 5 disclosure of Disclosure or Discovery Material in this Action. Any Party or Non-  
 6 Party that complies with this Order will be deemed to have taken reasonable steps to  
 7 rectify disclosures of privileged or protected Disclosure or Discovery Material.

8 (b) Each Party or Non-Party is entitled to decide the appropriate degree of care  
 9 to exercise in reviewing materials for Privileged Material, taking into account the  
 10 volume and sensitivity of the materials, the demands of the Action, and the resources  
 11 that the Party or Non-Party can make available.

12 (c) Except as otherwise provided herein, irrespective of the care that is actually  
 13 exercised in reviewing materials for Privileged Material, pursuant to Rule 502(d) of  
 14 the Federal Rules of Evidence, if, in connection with this Action, the Producing Party  
 15 discloses Privileged Material (“Disclosed Privileged Material”), the disclosure of the  
 16 Disclosed Privileged Material, whether inadvertent or otherwise, shall not constitute  
 17 or be deemed, either in this Action or any other action, investigation, or proceeding,  
 18 a waiver or forfeiture of any claim of any privilege or protection, including without  
 19 limitation the attorney-client privilege, the work product doctrine, or the deliberative  
 20 process privilege, that the Producing Party would otherwise be entitled to assert with  
 21 respect to the Disclosed Privileged Material and its subject matter. Any disclosure  
 22 shall also not be deemed a waiver or forfeiture as to any other document or  
 23 communication, whether concerning the same subject matter or a different subject  
 24 matter. The Parties shall not argue, in this forum or any other, that any privilege or  
 25 protection was waived as a result of disclosure in this Action, regardless of the  
 26 procedures used to identify Privileged Material prior to production.

27 (d) Notice of Disclosed Privileged Material. If a Producing Party determines  
 28 that it has produced Disclosed Privileged Material, the Producing Party shall, within

1 seven (7) calendar days of making such determination, provide written notice to all  
 2 counsel of record and identify the Disclosed Privileged Material (by date of  
 3 production and production number or range, if applicable) (“Disclosure Notice”).

4 (e) Any Party or Non-Party that receives a Disclosure Notice must: (a)  
 5 immediately cease reviewing and using the Disclosed Privileged Material; and (b)  
 6 within ten (10) calendar days of receipt of the Disclosure Notice: (i) return, sequester,  
 7 or destroy all copies of the Disclosed Privileged Material; (ii) upon request of the  
 8 Producing Party, provide to the Producing Party a certification of counsel that all of  
 9 the Disclosed Privileged Material has been returned, sequestered or destroyed; and  
 10 (iii) notify any Party or Non-Party to whom the Receiving Party has provided the  
 11 Disclosed Privileged Material that he, she, or it must comply with the obligations set  
 12 forth in this Section, including, upon request of the Producing Party, to provide to the  
 13 Producing Party a certification of counsel that all of the Disclosed Privileged Material  
 14 has been returned, sequestered or destroyed.<sup>2</sup>

15 (f) If a Party identifies Discovery Material that appears on its face to be  
 16 Disclosed Privileged Material belonging to another Party or Non-Party, the  
 17 identifying Party is under a good-faith obligation to notify that other Party or Non-  
 18 Party. Such notification shall not waive the identifying Party’s ability to subsequently  
 19 contest any assertion of privilege or protection with respect to the identified Discovery  
 20 Material. If the Party or Non-Party to which the Disclosed Privileged Material  
 21 belongs wishes to assert a claim of privilege or protection, that Party or Non-Party  
 22 shall provide a Disclosure Notice within seven (7) calendar days of receiving such  
 23 notification. Nothing in this Order overrides any attorney’s ethical responsibilities to  
 24

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25  
 26 <sup>2</sup> Copies of Disclosed Privileged Material that have been stored on electronic media  
 27 that is not reasonably accessible, such as disaster recovery backup media, are  
 28 adequately sequestered as long as they are not restored. If such data is restored, the  
 Receiving Party must take steps to re-sequester the restored Disclosed Privileged  
 Material.

1 refrain from examining or disclosing materials that the attorney knows or reasonably  
2 should know to be Privileged Material and to inform the Producing Party that such  
3 Privileged Material has been produced.

4 (g) Contesting a Claim of Privilege or Protection. A Party wishing to contest a  
5 claim of privilege or protection of this Order (the “Contesting Party”) shall, within  
6 seven (7) calendar days of receipt of the Disclosure Notice, provide written notice to  
7 the Producing Party of each such claim it is contesting (the “Contestation Notice”).  
8 Any Contestation Notice shall expressly refer to this Section of this Order, and shall  
9 describe the basis for the contestation. The Producing Party shall, within seven (7)  
10 calendar days of receiving a Contestation Notice, respond in writing by either: (i)  
11 agreeing to withdraw the claim of privilege or other protection; or (ii) stating the  
12 reasons for such claim. If the Contesting Party continues to dispute the claim(s) at  
13 issue, it shall notify the Producing Party in writing within seven (7) calendar days  
14 thereafter. The Parties shall attempt to resolve each contestation in good faith by  
15 conferring directly. A Contesting Party may proceed to the next stage of the  
16 contestation process only if he, she or it has engaged in this meet-and-confer process  
17 in a timely manner.

18 (h) If the relevant Parties or Non-Parties cannot resolve a contestation without  
19 court intervention, the Contesting Party may, within seven (7) calendar days of  
20 impasse, initiate the discovery dispute process provided under the Local Rules for an  
21 order overruling specific claims of privilege on which the Contesting Party and the  
22 Producing Party could not agree (“Contestation Motion”). Such Contestation Motion  
23 must be filed under seal in accordance with the Local Rules. The Contesting Party  
24 must not assert, as a ground for compelling disclosure, the fact or circumstances of  
25 the disclosure of the Discovery Material in this Action.

26 (i) While a Contestation Motion is pending, all Parties and Non-Parties shall  
27 continue to follow the procedures described herein, and no Party or Non-Party shall  
28 use the Disclosed Privileged Material for any other purpose nor disclose it to any

1 person other than those required by law to be served with a copy of the sealed motion.  
2 Nothing herein shall limit the right of any Party or Non-Party to petition the Court for  
3 an in-camera review of Disclosed Privileged Material. Privileged Material may not  
4 be filed in the public record in this Action.

5 (j) Depositions. If, during a deposition, a Party or Non-Party claims that a  
6 document being used in the deposition (e.g., marked as an exhibit, shown to the  
7 witness, or made the subject of examination) contains its Privileged Material, that  
8 Party or Non-Party may at his, her or its sole election (a) allow the document to be  
9 used during the deposition without waiver of his, her, or its claim of privilege or  
10 protection; or (b) instruct the witness not to answer questions concerning the parts of  
11 the document containing Privileged Material pending a prompt resolution of any  
12 disagreement concerning whether the document constitutes or contains Privileged  
13 Material. If the Party or Non-Party allows the examination concerning the document  
14 to proceed on a non-waiver basis, the Parties and any Non-Parties shall sequester all  
15 copies of the purportedly privileged or protected document. Immediately following  
16 the deposition, the Parties and any Non-Parties will commence the procedure,  
17 including the notice and log requirements to address the claim of privilege or other  
18 protection and any related disputes. Until any such disputes are resolved, all Parties  
19 and Non-Parties who have access to the transcript of such deposition shall treat the  
20 relevant portion of the transcript as Privileged Material. If any Party or Non-Party  
21 instructs the witness not to answer questions concerning the document on grounds of  
22 privilege, the Parties will cooperate in promptly following the procedures as  
23 applicable. The Parties may stipulate without the need for Court approval to narrow  
24 or extend the time periods specified in this Order.

## 25 **11. MISCELLANEOUS**

26 11.1 Right to Further Relief. Nothing in this Order abridges the right of any  
27 person to seek its modification by the Court in the future.

28 11.2 Right to Assert Other Objections. By stipulating to the entry of this

1 Protective Order, no Party waives any right it otherwise would have to object to  
2 disclosing or producing any information or item on any ground not addressed in this  
3 Stipulated Protective Order. Similarly, no Party waives any right to object on any  
4 ground to use in evidence of any of the material covered by this Protective Order.

5 11.3 Filing Protected Material. A Party that seeks to file under seal any  
6 Protected Material must comply with Local Civil Rule 79-5.

7 11.4 Party's Own Use of Protected Material. Nothing contained in this  
8 Protective Order shall preclude any Party from using its own Protected Material in  
9 any manner it sees fit, without prior consent of any Party or the Court.

## 10 **12. FINAL DISPOSITION**

11 After the conclusion of this Action, including all appeals, within sixty (60) days  
12 of a written request by the Designating Party, each Receiving Party must return all  
13 Protected Material to the Producing Party or destroy such material. As used in this  
14 subdivision, "all Protected Material" includes all copies, abstracts, compilations,  
15 summaries, and any other format reproducing or capturing any of the Protected  
16 Material. Whether the Protected Material is returned or destroyed, the Receiving Party  
17 must submit a written certification to the Producing Party (and, if not the same person  
18 or entity, to the Designating Party) by the 60 day deadline that (1) identifies (by  
19 category, where appropriate) all the Protected Material that was returned or destroyed  
20 and (2) affirms that the Receiving Party has not retained any copies, abstracts,  
21 compilations, summaries or any other format reproducing or capturing any of the  
22 Protected Material. Notwithstanding this provision, Counsel are entitled to retain an  
23 archival copy of all pleadings, motion papers, trial, deposition, and hearing  
24 transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert  
25 reports, attorney work product, and consultant and expert work product, even if such  
26 materials contain Protected Material. Any such archival copies that contain or  
27 constitute Protected Material remain subject to this Protective Order.

1 Dated: February 3, 2023

Respectfully submitted,

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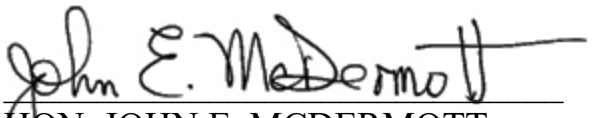
27 *Attorneys for Plaintiff Sandoz*  
28 *Inc.*



1           **GOOD CAUSE APPEARING**, the Court hereby approves this stipulated  
2 Protective Order.

3  
4           **IT IS SO ORDERED.**

5  
6 Dated: February 6, 2023

7   
8 HON. JOHN E. MCDERMOTT  
9 United States Magistrate Judge  
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**ATTESTATION**

I hereby attest that all signatories listed above, on whose behalf this Stipulation is submitted, concur in the filing's content and have authorized the filing.

Dated: February 3, 2023

By: /s/ Todd Benoff

Todd Benoff

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**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

SANDOZ INC.,  
Plaintiff,  
v.  
AMGEN INC.,  
Defendant.

Case No. 2:22-cv-05326-RGK-JEM

**STIPULATED PROTECTIVE  
ORDER: EXHIBIT A**

**EXHIBIT A**  
**ACKNOWLEDGEMENT AND AGREEMENT TO BE BOUND**

I, \_\_\_\_\_, declare under the penalty  
of perjury that:

1. My address is

\_\_\_\_\_.

My current employer is

\_\_\_\_\_.

My current occupation is

\_\_\_\_\_.

2. I have received a copy of the Stipulated Protective Order that was issued by the United States District Court for the Central District of California in the case of *Sandoz Inc. v. Amgen Inc.*, Case No. 2:22-cv-05326-RGK-JEM. I have carefully read and understand the provisions of the Protective Order.

3. I agree to comply with and to be bound by all of the terms of the Stipulated Protective Order.

4. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Stipulated Protective Order to any person or entity except in strict compliance with the provisions of this Order.

5. I further agree to submit to the jurisdiction of the United States District Court for the Central District of California for enforcing the terms of this Stipulated Protective Order, even if such enforcement proceedings occur after termination of this action.

6. Promptly upon termination of these actions, I will return all documents and things designated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY" that came into my possession, and all documents and things that I have prepared relating thereto, to the outside

1 counsel for the Party by whom I am employed. Alternatively, I will promptly  
2 destroy all such material.

3  
4 I declare under penalty of perjury that the foregoing is true and correct.

5 Date \_\_\_\_\_

6 City and State Where Sworn and Signed \_\_\_\_\_

7 Printed Name \_\_\_\_\_

8 Signature \_\_\_\_\_